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MORRISON ULMAN
WOODSIDE IP GROUP 1900 EMBARCADERO ROAD SUITE 209
PALO ALTO, CA 94303-3327

EXAMINER	
MALLARI, PATRICIA C	
ART UNIT	**PAPER NUMBER**
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/709,014	BANET, MATTHEW J.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 4/7/04.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 07 April 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Objections

Claims 1, 7 and 15 are objected to because of the following informalities:

On line 1 of claim 1, "patient"s" should be replaced with "patient's";

On lines 1-2 of claim 7, "the optical module further comprises" should be replaced with "the optical source of the optical module comprises";

On line 3 of claim 9, "the first and second optical sources" should be replaced with "the first optical source and a second optical source";

on line 2 of claim 15, "user"s" should be replaced with "user's". Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, and 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, and 6 of copending Application No. 10/709015 (herein referred to as application '015). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of application '015 recites an optical module comprising an optical source and an optical detector (lines 4-5), a thin-film pressure–monitoring module (lines 2-3), and a microprocessor configured to receive and process information from the pressure-monitoring module and the optical module to determine blood pressure (lines 6-8). While not explicitly recited in the claim, the optical module of claim 1 of application '015 clearly generates a first set of information, since some information is recited as being sent to the microprocessor on lines 6-7 of the claim. Therefore, the optical modules of claim 1 of the instant application and of claim 1 of application '015 are clearly equivalent. Similarly, the pressure module of claim 1 of application '015 is equivalent to the pressure sensor of claim 1 of the instant application and generates information disclosed as being sent to the microprocessor on lines 6-8 of the claim. Lastly, the microprocessor of claim 1 of application '015 is clearly equivalent to the processing module of claim 1 of the instant application. Since claim 1 of the instant application is anticipated by claim 1 of application '015, it is not patentably distinct from claim 1 of application '015.

Regarding claim 2 of the instant application, a pressure-monitoring module having a pressure-sensitive region is a sensor that generates a response to an applied force or pressure.

Regarding claim 8 of the instant application, claim 5 of application '015 recites the optical detector being a photodiode.

Regarding claim 17 of the instant application, claim 6 of application '015 recites that the device further comprises a finger-mounted component that comprises the optical module.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 3 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/709,015 in view of US Patent No. 6,700,174 to Miu et al. Claim 1 of application '015 fails to describe the thin film pressure monitoring module in depth. However, Miu discloses a thin film pressure monitoring module having a pressure sensitive region 221-224 (fig. 2 of Miu), wherein the sensor comprises a sensing material featuring an electrical resistance that varies with an applied force (col. 5, lines 23-50 of Miu). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the sensor of Miu as that of claim 1 of application '015, since claim 1 cites a thin film pressure monitoring module having a pressure sensitive region, and Miu discloses such a module.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6,12, 13, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,538,729 to Khair et al. in view of US Patent No. 6,814,705 to Kawaguchi. Khair discloses a device for monitoring a patient's blood pressure (col. 6, lines 12-16 of Khair). The device comprises an optical module comprising an optical source component 30 and a first optical sensor 18 that generates a first set of information (fig. 3; col. 6, lines 26-37 of Khair). A hold down pressure sensor 36 generates a second set of information (fig. 3; col. 8, lines 23-41 of Khair). A processing module 100 is configured to receive the first and second sets of information and comprises a processor 112 that processes this information to calculate a blood pressure value (figs. 12, 14; col. 13, line 5-41; col. 15, lines 21-37 of Khair). Khair teaches that the hold down pressure sensor comprises a strain gauge, which may be of the semiconductor type, but fails to specify that the sensor is of the thin film type.

However, Kawaguchi teaches a non-invasive blood pressure measuring device wherein a pressure transducer may equivalently be of semiconductor or of a thin-film type (col. 11, lines 5-12 of Kawaguchi). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a thin-film sensor as the hold down

pressure sensor of Khair, since Kawaguchi discloses that a semiconductor and a thin film pressure sensor are functionally equivalent in pressure sensing.

Regarding claims 2-4, the pressure sensor 36 generates the second set of information in response to an applied force or pressure (col. 7, lines 21-23; col. 8, lines 23-28 of Khair). With further regard to claims 3 and 4, the pressure sensor 36 comprises a sensing material featuring an electrical resistance that varies with applied force or pressure (col. 8, lines 27-41 of Khair). With further regard to claim 4, the pressure sensor 36 is configured to generate a time-dependent pressure waveform that varies in response to an applied pressure or force (fig. 11; col. 11, line 53-col. 12, line 3 of Khair).

Regarding claims 5 and 6, the processing module 100 further comprises an A/D converter 110 (fig. 12 of Khair). With further regard to claim 6, the pressure sensor 36 is in electrical contact with the converter 110 (fig. 12; col. 12, lines 13-21 of Khair).

Regarding claims 12 and 13, the processor 112 comprises computer-readable firmware that processes the first and second sets of information to determine systolic and a diastolic blood pressure (fig. 1; col. 6, lines 43-60;col. 13, lines 22-38 of Khair). With further regard to claim 13, the processor further comprises computer-readable firmware that processes the first and second sets of information to determine a time-dependent blood pressure (fig. 10; col. 9, lines 13-19 of Khair).

Regarding claims 15 and 16, an adjustable band 11, 13 is configured to attach to a user's wrist (fig. 1; col. 7, lines 5-7 of Khair). With further regard to claim 16, the band

11, 13 comprises the pressure sensor 36, wherein the pressure sensor 36 is part of the optical sensor 12 (figs. 1-3; col. 6, lines 25-28; col. 12, lines 41-50 of Khair).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,027,455 to Inukai et al. in view of Khair and further in view of Kawaguchi. Inukai discloses an apparatus 8 comprising an optical module 38, the optical module having a first sensor 46 and an optical source 44a, 44b. The apparatus 8 also comprises a processor 29 that receives information from the optical module 38 and uses it to calculate blood pressure (col. 9, lines 48-60; col. 11, lines 1-61of Inukai). The optical module 38 comprises a first optical source 44a emitting visible radiation, and a second source 44b emitting infrared radiation (col. 9, lines 29-34 of Inukai). The processor 29 comprises computer readable firmware that processes information from the optical module to determine pulse oximetry. Inukai lacks a flexible thin-film pressure sensor.

However, Khair teaches a blood pressure measuring device that utilizes an optical module to obtain a pulse wave from which the blood pressure is determined. A flexible pressure sensor 36 generates a set of information utilized by the processor 100 in conjunction with the information from the optical module to determine blood pressure (col. 8, lines 23-42; col. 15, lines 21-37 of Khair). The pressure sensor 36 determines hold down pressure, which is used to calibrate the blood pressure sensor, thereby making the blood pressure readings more accurate (col. 4, lines 4-12 of Khair). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the apparatus of Khair with that of Inukai in order to yield more

accurate blood pressure measurements. Inukai, as modified by Khair fails to describe the pressure sensor as being of a thin-film type.

However, Kawaguchi teaches a non-invasive blood pressure measuring device wherein a pressure transducer may equivalently be of semiconductor or of a thin-film type (col. 11, lines 5-12 of Kawaguchi). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a thin-film sensor as the hold down pressure sensor of Inukai, as modified by Khair, since Kawaguchi discloses that a semiconductor and a thin film pressure sensor are functionally equivalent in pressure sensing.

Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khair in view of Kawaguchi, as applied to claims 1-6,12, 13, 15, and 16 above, and further in view of US Patent No. 5,237,997 to Greubel et al. Khair, as modified discloses photodetectors 18 is silent as to any details about them. However, Greubel discloses a blood pressure measuring device comprising a light sensor, wherein the detecting portion of the sensor is a photodiode (col. 3, lines 38-42 of Greubel). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a photodiode as the photodetector of Khair, since Khair discloses using a light detector, and Greubel describes a photodiode as an appropriate such light detector.

Regarding claims 9-11, the photodiode is configured to generate a photocurrent after detecting radiation generated by the optical sources (col. 7, lines 54-67 of Khair). With further regard to claim 10, the processing module 100 comprises an A/D converter

110 configured to receive and process the photocurrent (fig. 12 of Khair). With further regard to claim 11, the processing module 100 comprises firmware that processes the photocurrent to generate a time-dependent optical waveform (fig. 10; col. 9, lines 5-19 of Khair).

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Inukai in view of Khair and Kawaguchi, as applied to claim 7, and further in view of US Patent No. 5,297,554 to Glynn. Inukai, as modified, discloses that the heart rate is determined by the processor 29, but that the calculation of heart rate is based on input from ECG electrodes rather than on input from the optical module, wherein the optical module of Inukai is employed as part of a pulse oximeter (fig. 2; col. 9, lines 1-5; col. 11, lines 1-6 of Inukai). However, Glynn teaches that pulse rate, which is equivalent to heart rate, may be determined either from an oximeter measurement or from an ECG measurement (col. 1, lines 36-38 of Glynn). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to determine the heart rate in the apparatus of Inukai based on the oximeter measurement rather than based on the ECG electrode measurement, since Glynn teaches that the two sources of information for heart rate determination are equivalent.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Khair in view of Kawaguchi, as applied to claims 1-6,12, 13, 15, and 16 above, and further in view of US Patent No 5,752,920 to Ogura et al. Khair, as modified fails to disclose a finger worn component that comprises the optical module. However, Ogura disclose a blood pressure measuring device, wherein a pulse wave sensor, from which blood

pressure measurements are derived, may be placed on either a wrist or a finger. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to configure the device, including the band of Khair, as modified by Kawaguchi, to be placed on a finger, rather than a wrist of the patient, since Ogura teaches the placement on a finger and on a wrist as being functionally equivalent for determining blood pressure using a pulse wave sensing device.

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khair in view of Kawaguchi, as applied to claims 1-6,12, 13, 15, and 16 above, and further in view of US Patent No. 6,093,146 to Filangeri. Khair, as modified, teaches that the device may employ a wireless transceiver module 122 but is silent as to how the connection between the microcontroller 112 and the transceiver module 122 is effected. However, Filangeri discloses data transmission from a microcontroller 36 to an RF transceiver 40 through a serial port, wherein the RF transceiver 40 then transmits the information to an external device (fig. 2; col. 7, lines 7-18 of Filangeri). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a serial port for transmission between the transceiver module and the microcontroller of Khair, since Khair discloses data transmission between a transceiver module and microcontroller, and Filangeri teaches that a serial port is an appropriate means of such data transmission.

Regarding claims 19 and 20, the serial interface is configured to send information to an external device (fig. 1; col. 13, lines 35-52 of Khair). As to the language "calibration information" in claim 20, the applicants should note that the term

"calibration" is merely "intended use" language that cannot be relied upon to overcome the applied references, since the combined references of Khair and Kawaguchi teach all of the claimed elements and their recited relationships. Since a serial interface is an interface for transmitting and receiving signals (see "serial interface", *Collins Dictionary of Computing*), the interface 210 of Khair, as modified, is clearly capable of accepting any information.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Mallari

Robert E. Nasser